

Request for Continued Examination

Included herewith is a Request for Continued Examination (RCE) of the present application and a check for the RCE filing fee.

Declaration

Also included herewith is a declaration under 37 CFR § 1.132 in support of the patentability of the pending claims. Applicant respectfully requests reconsideration of the rejections under 35 U.S.C. § 103 in light of this declaration and the following remarks.

35 U.S.C. § 103(a) Rejections

The Examiner rejected claims 1-12 and 14 under 35 U.S.C. § 103(a) over Jyonouchi et al., Abstract No. 1994:321921 CAPLUS; in view of Anon., Accession No. 97:19:19144 BIOBUSINESS, Ito et al., which the Examiner asserts is U.S. Patent No. 5,993,714 but Applicant assumes the Examiner refers to U.S. Patent No. 5,937,790; Krinsky, Accession No. 91090021 MEDLINE; and further in view of page 11 of CRC Handbook of Toxicology, Derelanko and Hollinger, eds., the date of which the Examiner asserts is 1995 (see the Office Action mailed April 11, 2000). This rejection is respectfully traversed.

The present claims are directed to a process for “enhancing immune response of a companion animal” (Claim 1), “increasing lutein concentration in the circulating blood of a companion animal” (Claim 9), “increasing immunoglobulin concentration in a companion animal” (Claim 10), and “increasing lymphocyte cells in a companion animal” (claim 11), by feeding the animal a specific lutein containing diet, “for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.”

Jyonouchi et al. reports that lutein may affect the humoral immune response of a mouse spleen following intraperitoneally (IP) injected lutein. The Examiner stated in the Advisory Action that since lutein has been proven to be effective to improve immune response in the mouse, the instant claims are obvious over the disclosure of Jyonouchi et al. in view of the secondary references.

Applicant respectfully submits that the effects of the intraperitoneal (IP) injection of lutein reported in Jyonouchi et al. would not suggest to one skilled in the art that the dietary administration of lutein would have any effect on the immune response of a companion animal (as recited by the instant claims). In support of this position, Applicant provides herewith, a Declaration of inventor Dr. Michael Hayek (hereinafter "Hayek Declaration"). Dr. Hayek is a skilled worker in the field of companion animal nutrition. The Hayek Declaration concludes that one skilled in the art could not have reasonably inferred from the information reported in Jyonouchi et al. that "lutein would be absorbed at effective levels following oral administration so as to have the claimed effect on the immune system and immune response in companion animals." Hayek Declaration at ¶ 6. It is respectfully submitted that the secondary references also fail to suggest that oral administration of lutein would have any of the therapeutic effects recited by the instant claims. Thus, the cited documents would not have provided one skilled in the art with reasonable expectation that the oral administration of lutein would provide the beneficial effects recited in the instant claims. Thus, the cited documents do not suggest the claimed invention. Accordingly, withdrawal of the rejection over Jyonouchi et al., in combination with the secondary references is requested.

The Examiner also rejected claims 1-12 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Ito et al. This rejection is respectfully traversed.

The Advisory Action stated that "[since] lutein is known to be useful as food supplements for improve [sic] health of animal [sic] in general, [sic] immune response in particular, it is *prima facie* obvious to feed lutein to animals in need to improve health conditions."

It is respectfully submitted that even if it is true, *arguendo*, that "lutein is known to be useful as a food supplement to improve the health of animals in general," as stated by the Examiner, it would not render the instant claims *prima facie* obvious. In Applicant's previous response (paper no. 25, page 6-8) considerable argument was presented to address the rejection over Ito et al. Since the Examiner failed to address any of the arguments presented, they are duplicated hereinbelow. If the Examiner maintains the rejection over Ito et al., it is respectfully requested that the Examiner specifically address the arguments presented.

The Examiner is respectfully requested to consider that a "new use" of a composition is clearly patentable subject matter 35 U.S.C. § 100(b). The present claims are directed to previously unknown uses for a composition comprising lutein, which are based on the discovery that, *inter alia*, dietary administration of lutein enhances the immune response of companion animals. 35 U.S.C. § 101. To render such a claim obvious, the obviousness of the claimed result must be apparent to one of skill in the art from the prior art, viewed without the benefit of knowledge of Applicant's invention. Thus, even if dietary administration of lutein is "generally known", there is nothing in the cited art to suggest that the dietary administration of lutein would have any beneficial effect on the immune response of a cat or a dog.

In Ex parte Levengood, 28 USPQ2d 1300 (Bd. App. 1993) (copy enclosed), the Examiner noted that because all aspects of the invention were well known to the art, the claimed method was "well within the ordinary skill of the art at the time the claimed invention was made." The Board reversed the obviousness rejection, stating

at best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness. See Orthokinetics Inc. v. Safety Travel Chairs Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). That which is within the capabilities of one skilled in the art is not synonymous with obviousness. Ex parte Gerlach, 212 USPQ 471 (Bd. App. 1980). See also footnote 16 of Panduit Corp. v. Dennison Mfg. Co., 774 F.2d 1082, 1092, 227 USPQ 337, 343 (Fed. Cir. 1985).

The Examiner is also respectfully requested to note that the fact that lutein may previously have been suggested as a possible ingredient in a food stuff does not render the claimed use of lutein obvious in the absence of a suggestion that the beneficial therapeutic results recited by the claimed methods would occur. None of the cited documents teach or suggest that oral administration of lutein would have any effect on an animal's immune system or would increase the concentration of lutein in an animal's blood. Thus, is respectfully submitted that *prima facie* obvious has not been established. Withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

AMENDMENT & RESPONSE UNDER 37 C.F.R. § 1.116 - EXPEDITED PROCEDURE

Serial Number: 09/291,227

Filing Date: April 13, 1999

Title: LUTEIN - CONTAINING SUPPLEMENT AND PROCESS FOR ENHANCING IMMUNE RESPONSE IN ANIMALS

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Dkt: 1448.019US1

Conclusion

In light of the above remarks and the enclosed declaration, Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6961) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

MICHAEL GRIFFIN HAYEK

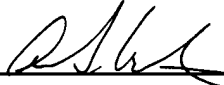
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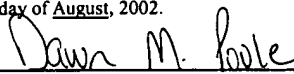
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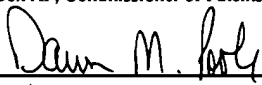
Date 14 August 2002 By 

Ann S. Viksnins

Reg. No. 37,748

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Box AF, Commissioner of Patents, Washington, D.C. 20231, on this 14th day of August, 2002.


Name


Signature